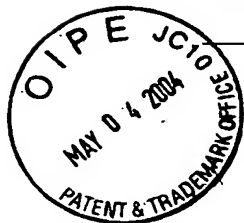


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| Application of: | Paul S. Keim et al. | : | Group Art Unit: | 1634 |
| Serial No.: | 10/624,714 | : | Examiner: | Unassigned |
| Filed: | 07-21-2003 | : | Docket No.: | 112624.00085 ORD |
| For: | High Resolution Typing System for Pathogenic Mycobacterium Tuberculosis | | | |

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| For: | High Resolution Typing System for Pathogenic Mycobacterium Tuberculosis | | | |

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97

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Respectfully submitted,

QUARLES & BRADY STREICH LANG, LLP

Dated: April 29, 2004

By: Barbara J. Luther
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Sheet 1 of 3

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| Application Number | 10/624,714 |
| Filing Date | 07-21-2003 |
| First Named Inventor | Keim et al. |
| Group Art Unit | 1645 |
| Examiner Name | t.b.d. |
| Attorney Docket Number | 130588.91451 ORD |

[illegible][illegible]Date
Considered

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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| | | | Filing Date | 07-21-2003 | |
| | | | First Named Inventor | Keim et al. | |
| | | | Group Art Unit | 1645 | |
| | | | Examiner Name | t.b.d. | |
| Sheet | 2 | of | 3 | Attorney Docket Number | 130588.91451 ORD |

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| | 6 | ..., "Global Tuberculosis Control Report", World Health Organization, pg 6, 2002. | |
| | 7 | Bifani, P., et al., "Global dissemination of the mycobacterium tuberculosis W family strains", article, Trends in Microbiology 10:45-52, 2002. | |
| | 8 | Braden, C., et al., "Assessment of Mycobacterium tuberculosis Genotyping in a Large Laboratory Network", article, Emerging Infec Diseases 8(11):1210-5, 2002 November. | |
| | 9 | Castro, K., et al., "Rationale and methods for the national tuberculosis genotyping and surveillance network", article, Emerging Infec Diseases 8(11):88-91, 2002. | |
| | 10 | Cowen, L., et al., "Variable-Number Tandem Repeat Typing of Mycobacterium tuberculosis Isolates with Low Copy Numbers of IS6110 by Using Mycobacterial Interspersed Repetitive Units", article, J Clin Microb 40:1592-602. 2002. | |
| | 11 | Dale, J., et al., "Spacer oligonucleotide typing of Mycobacterium Tuberculosis: recommendations for standardized nomenclature", article, Int J Tuberc Lung Dis, 5:216-19, 2001. (abstract) | |
| | 12 | Fang, Z., et al., "Molecular evidence for independent occurrence of IS6110 insertions at the same sites to the genome of Mycobacterium tuberculosis in different clinical isolates", article, J Bacteriol 183:5279-5284, 2001. | |
| | 13 | Farlow, J., et al., "Francisella tularensis strain typing using multiple-locus, variable-number tandem repeat analysis", article, J Clin Microb, 39:3186-92, 2001. | |
| | 14 | Frothingham, R., et al., "Genetic diversity in the Mycobacterium tuberculosis complex based on variable numbers of tandem DNA repeats", article, Microbiology 144:1189-96, 1998. | |
| | 15 | Kamerbeek, J., et al., "Simultaneous detectin and strain differentiation of Mycobacterium tuberculosis for diagnosis and epidemiology", article, J Clin Microbiol 35:907-14, 1997. | |
| | 16 | Keim, P., et al., "Multiple-locus variable-number tandem repeat analysis reveals genetic relationships within Bacillus anthracis", article, J of Bacteriol 182:2928-36, 2000. | |

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| | | First Named Inventor | Keim et al. |
| | | Group Art Unit | 1645 |
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| | 17 | Kremer, K., et al., "Comparison of methods based on different molecular epidemiological markers for typing of Mycobacterium tuberculosis complex strains: interlaboratory study of discriminatory power and reproducibility. J Clin Microbiol 37:2607-18, 1999. | |
| | 18 | Le Fleche P. et al., "High resolution, on-line identification of strains from the Mycobacterium tuberculosis complex based on tandem repeat typing". BMC Microbiol. 37:1-12, 2002 | |
| | 19 | Mazars, E. et al., "High-resolution minisatellite-based typing as a portable approach to global analysis of Mycobacterium tuberculosis molecular epidemiology". Proceedings of Natl Acad Sci US. 98:1901-6. 2001. | |
| | 20 | Quitugua, T. et al., "Transmission of drug resistant tuberculosis in Texas". J Clin Microbiol. 40:8. 2716-24, 2002. | |
| | 21 | Skuce, R. et al., "Discrimination of Mycobacterium tuberculosis complex bacteria using novel VNTR-PCR targets". Microbiology. 148:519-28. 2002. | |
| | 22 | Sola, C. et al., "Spoligotype database of Mycobacterium tuberculosis: biogeographic distribution of shared types and epidemiologic and phylogenetic perspectives". Emerging Infectious Diseases. 7:390-6. 2001. | |
| | 23 | Sola, C. et al., "Mycobacterium tuberculosis phylogeny reconstruction based on combined numerical analysis with IS1081, IS6110, VNTR, and DR-based spoligotyping suggests the existence of two new phylogeographical clades". J Molec Ev. 53:680-9. 2001 | |
| | 24 | Supply, P. et al., "Automated high-throughput genotyping for study of global epidemiology of Mycobacterium tuberculosis based on mycobacterial interspersed repetitive units". J Clin Microbiol 39:3563-71. 2001. | |
| | 25 | Supply, P. et al., "Identification of novel intergenic repetitive units in a mycobacterial two-component system operon". Molec Microbiol. 26:991-1003. 1997. | |
| | 26 | Supply, P. et al., "Variable human minisatellite-like regions in the Mycobacterium tuberculosis genome". Molec Microbiol. 36:762-71. 2000. | |
| | 27 | van Embden, J. et al., "Strain identification of Mycobacterium tuberculosis by DNA fingerprinting: recommendations for a standardized methodology". J Clin Microbiol 31:406-9. 1993. | |

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